



Food and Drug Administration
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January 26, 2015

Penumbra, Inc.
Ms. Michaela Mahl
Senior Manager, Regulatory Affairs
1351 Harbor Bay Parkway
Alameda, California 94502

Re: K142321
Trade/Device Name: Benchmark Intracranial Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 15, 2014
Received: December 16, 2014

Dear Ms. Michaela Mahl,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carlos L. Pena -SDA

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142321

Device Name

Benchmark Intracranial Access System

Indications for Use (Describe)

The Benchmark™ Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra Inc. is providing the summary of Substantial Equivalence for the Benchmark™ Intracranial Access System.

7.1 Sponsor/Applicant Name and Address

Penumbra, Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502, USA

7.2 Sponsor Contact Information

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Senior Manager, Regulatory Affairs
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7.3 Date of Preparation of 510(k) Summary

January 20, 2015

7.4 Device Trade or Proprietary Name

Benchmark™ Intracranial Access System

7.5 Device Classification

Regulatory Class: II
Classification Panel: Cardiovascular
Classification Name: Percutaneous Catheter
Regulation Number: 21 CFR § 870.1250
Product Code: DQY

7.6 Predicate Devices

510(k) Number / Clearance Date	Name of Predicate Device	Name of Manufacturer
K082290 / 31Oct2008	Neuron Delivery Catheter 070	Penumbra, Inc.
K083125 / 21Nov2008	Neuron Select Catheter 070	Penumbra, Inc.

7.7 Predicate Comparison

System Name	Neuron Intracranial Access System	Benchmark Intracranial Access System
Device Name	Neuron 070 Delivery Catheter	Benchmark Delivery Catheter
510(k) No.	K082290	K142321
Classification	Class II, DQY	SAME
Indication	The Neuron Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Benchmark Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Catheter Materials	Commonly used medical grade plastics & stainless steel	SAME
Outer Dimension	6F (0.081 in -0.083 in)	SAME
Inner Dimension	0.070 in Min	SAME
Effective Length	95 cm, 105 cm	95 cm, 105 cm, 115 cm
Tip Shapes	Straight & Multi-Purpose	SAME
Packaging Materials	Commonly use medical device packaging materials	SAME
Sterilization	EtO	SAME
Shelf-Life	36 Months	12 Months [36 Months in-process]

System Name	Neuron Intracranial Access System	Benchmark Intracranial Access System
Device Name	Neuron Select Catheter 070	5F Select Catheter
510(k) No.	K083125	K142321
Classification	Class II, DQY	Class II, DQY
Indication	The Neuron Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Benchmark Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Catheter Materials	Commonly used medical grade plastics & stainless steel	SAME
Outer Dimension	5F (0.069in Max)	SAME
Inner Dimension	0.043 in Max	SAME
Effective Length	123 cm & 131.5cm	SAME
Tip Shapes	Berenstein, H1 & Simmons	SAME
Packaging Materials	Commonly use medical device packaging materials	SAME
Sterilization	EtO	SAME
Shelf-Life	36 Months	SAME

7.8 Device Description

The Benchmark™ Intracranial Access System is designed to aid the physician in accessing the target vasculature during interventional procedures. Benchmark Intracranial Access System is composed of a Delivery Catheter (guide catheter) used to support other diagnostic or therapeutic devices and a corresponding Select Catheter (microcatheter). Use of the Benchmark Intracranial Access System facilitates navigation to the target vascular location and delivery of the necessary diagnostic and/or therapeutic agents. The Benchmark Intracranial Access System devices are compatible with off-the-shelf accessories. Various lengths and distal shapes of both the Benchmark Delivery Catheter and 5F Select Catheter are provided for physician convenience.

7.9 Indications for Use

The Benchmark™ Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

7.10 Summary of Non-Clinical Data

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, a summary of any information regarding safety and effectiveness of the device follows.

Included in this section are descriptions of the testing's, which substantiates the safe and effective performance of the Benchmark™ Intracranial Access System as well as its substantial equivalence to the predicate devices:

- Biocompatibility
- Design Verification (Bench-Top Testing)

The subject Benchmark™ Intracranial Access System met all established requirements.

7.10.1 Biocompatibility Testing

Biocompatibility tests conducted on the materials of the Benchmark™ Intracranial Access System were selected in accordance with EN ISO 10993 -1 guidelines (Biological Evaluation of Medical Devices) for limited duration (<24 hours), external communicating devices, contacting circulating blood. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. In summary, non-clinical testing found the Benchmark™ Intracranial Access System to be biocompatible according to the requirements of EN ISO 10993 requirements. The following tests were performed and all tests passed successfully:

Test	Acceptance Criteria	Results	Pass / Fail
<i>In Vitro</i> Cytotoxicity	Sample extracts must yield cell lysis grade 2 or lower	Grade 0-1: None to Slight	Pass
Sensitization	Test Group shall yield Grade < 1 score on Magnusson and Kligman scale (provided control Grade < 1)	Grade 0: No visible change	Pass
Acute Intracutaneous Reactivity (Irritation)	The difference in the mean test article and mean control score must be grade 1.0 or lower	Grade \leq 1.0 difference between mean test article and mean control score	Pass
Systemic Toxicity			
Acute Systemic Toxicity	Sample extracts must not cause the following: <ul style="list-style-type: none"> • > 10% weight loss in 3 or more test animals • Mortality of 2 or more test animals • Abnormal behavior in 2 or more test animals 	No evidence of systemic toxicity from sample extracts <ul style="list-style-type: none"> • No weight loss • No death • All test animals appeared normal 	Pass
Rabbit Pyrogen Study	Sample Extracts must not cause a total rise in body temperature of $\geq 0.5^{\circ}\text{C}$	Non-pyrogenic: No evidence of material-mediated pyrogenicity; no single animal had a total body temperature rise of $\geq 0.5^{\circ}\text{C}$	Pass
Hemocompatibility			
<i>In Vitro</i> Hemolysis [Extract Methode]	Sample extracts must be non-hemolytic ($\leq 2\%$ hemolytic index)	Non-hemolytic: Hemolytic Index = 0.70% - 1.04% Corrected Hemolytic index = 0.00% - 0.23%	Pass
Complement Activation	The concentrations of C3a and SC5b-9 in the test samples are statistically similar to the predicate (Exposure Control & Ref Material) control and statistically lower than the positive control for all exposure times	The test sample concentrations of C3a and SC5b-9 were statistically similar or lower than the predicate control sample concentrations, and statistically lower than the positive control sample concentration	Pass
Dog Thrombogenicity	The device must be non-thrombogenic after 4 hours <i>in vivo</i> when compared to a control device	Test Device was non-thrombogenic after 4 hours <i>in vivo</i> when compared to a control device	Pass

7.10.2 Bench-top Testing

The physical and mechanical properties of the Benchmark™ Intracranial Access System were assessed using standard test methods and pre-determined acceptance criteria. The following tests were performed and all tests passed successfully:

Attribute	Sample Size	Specification	Acceptance Criteria	Results
Dimensional/ Visual Inspection		These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of finished goods (clinically acceptable) product.		Pass
Simulated Use [Intracranial Access & Vessel Access Entry Performance]		Simulated use testing of the Benchmark Delivery Catheter and Benchmark Select Catheter was performed with accessory devices in an anatomical model which simulated the tortuosity of the neurovasculature.		Pass
Catheter Coating Integrity	N=30	Coating has not delaminated, peeled, or flaked after simulated use	100% Must meet Specification	100% Pass
	N=10	Coating has not further delaminated, peeled, or flaked from coating integrity baseline	100% Must meet Specification	100% Pass
Particulate Testing (Catheter Hydrophilic Coating)	N=10	The maximum number of particles: ≤ 6000 particles ≥ 10 µm ≤ 600 particles ≥ 25 µm ≤ 600 particles ≥ 75 µm 0 particles ≥ 125 µm	100% Must meet Specification	<u>10µm</u> - 100% Pass <u>25µm</u> - 100% Pass <u>75 µm</u> - 100% Pass <u>125 µm</u> - 100% Pass
Hub/Catheter Air Aspiration	N=30	When negative pressure is pulled, no air may leak into hub	100% Must meet Specification	100% Pass
Pressure Test	N=30	45 psi for 30 sec MIN	100% Must meet Specification	100% Pass
Benchmark Delivery Catheter / Sheath compatibility (Friction Force)	N=30	Maximum value per specification	100% Must meet Specification	100% Pass
Benchmark Delivery Catheter / Benchmark Select Catheter compatibility (Friction Force)	N=30	Maximum value per specification	100% Must meet Specification	100% Pass
Catheter Shaft Tensile Strength (includes all joints)	N=30	Minimum value per specification	100% Must meet Specification	100% Pass

Attribute	Sample Size	Specification	Acceptance Criteria	Results
Hub to Shaft & Hub to Hypotube Bond Strength	N=30	Minimum value per specification	100% Must meet Specification	100% Pass
Elongation to Failure – Catheter	N=30	% Elongation \geq 5%	100% Must meet Specification	100% Pass

The results of the tests appropriately address the physical and mechanical performance expectations of the device. Based on these overall results, the physical and mechanical properties of the Benchmark™ Intracranial Access System are acceptable for the intended use and substantially equivalent to the predicate device.

7.10.3 Animal Study

No animal study was required.

7.10.4 Summary of Substantial Equivalence

The Benchmark™ Intracranial Access System is substantially equivalent to the predicate device with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.